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Review of

Liguria Foods, Inc. v. Griffith Laboratories, Inc.

Case no. 2014 cv 3041

Expert Report submitted by

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This report is an assessment of information related to the case of Liguria Foods, Inc. v. Griffith Laboratories, Inc. in which a pepperoni product produced by Liguria Foods developed fading and discoloration of sliced pepperoni, resulting in customer complaints and eventually, loss of several customers. At issue is the cause of the fading and discoloration of the pepperoni.

This assessment report is based on documents and materials produced in this litigation, as well as publications from the peer-reviewed scientific literature, all of which are referenced in this report and some of which are attached to this report. The documents originating from the case that were reviewed for this report include the Complaint and Jury Demand, Defendant Griffith Laboratories, Inc.'s Answer and Affirmative Defenses to Plaintiff's Complaint and Jury Demand, depositions of Louis Windecker, Donald Connor, James Whitham, James Bacus, Jehan Saulnier, Sanny Shah, Joe Christopherson, Kathy Adams, Darrell Portz, Geroge Neill and Lynda Lathrop, and expert reports by Dr. David Dickey and Dr. Andrew Milkowski.

Summary of Assessment and Resultant Opinions

There is little doubt, based on observations by several individuals and the documents reviewed, that discoloration of the pepperoni in question occurred. However, it is my opinion that the claim (Complaint and Jury Demand, Common Factual Allegations nos. 20 and 21) of inadequate mixing of the spice block (Optimized Pepperoni Seasoning no. 17-2112), is only one of several possible explanations (described later in this report) for the pepperoni discoloration. The discoloration observed in this case cannot be attributed to a single cause, based on the information provided.

It is also my opinion that the claim of inadequate mixing of the spice block is based primarily on a hypothesis and circumstantial evidence. The reason for this opinion is that I could not find analytical data in the documents reviewed that demonstrate, to a reasonable degree of scientific certainty, a

direct cause-and-effect relationship between the mixing process for the spice block and the discoloration of the pepperoni in question.

It is important to note that the paprika used to characterize pepperoni with its orange-red color is highly susceptible to color fading and must be protected from light, air and oxidative conditions to provide a useful color life without unacceptable loss of color. In the case of pepperoni, which is exposed to a variety of conditions during processing, storage and distribution that promote oxidation, retention of paprika color is particularly challenging. This means that, for pepperoni, if any of the ingredients, processes or packaging used for the product are less than ideal, the likelihood of discoloration is increased significantly. Further, because several different factors are critically important to maintenance of stable pepperoni color, a small variation in two or more of these factors, each of which may be insignificant alone, but may in combination, provide a cumulative detrimental effect on color. In such a case, color loss cannot be attributed to a single cause.

Background Facts of the Case

In 2012 and early 2013, Liguria Foods noted an increasing number of customer complaints about discoloration of pepperoni slices. The discoloration was described by James Whitham as occurring on "edges and spots" of the slices (LIGURIA/GRIFF 004814) in a "sporadic" and "not widely seen" occurrence (LIGURIA/GRIFF 002185). Liguria Foods subsequently investigated the problem by looking for commonalities in the pepperoni process that were associated with the discolored products. In addition, several analyses were conducted on the discolored product including proximate composition, bacterial counts, fatty acid profiles, rancidity measurements, acidity level, pH, A_w and antioxidant (BHA, BHT) concentrations of both normal and discolored areas of the pepperoni. Antioxidant content of the spice block that was used for the discolored pepperoni was also measured. Because the greatest number of complaints appeared to be associated with the 19319 Regular Grind Pepperoni which was produced

with the 17-2112 spice block, Liguria Foods focused on the 17-2112 spice block that was used for the discolored pepperoni as a potential source of the problem. Subsequent discussions with Griffith Laboratories about changes in the spice mixture did not fully satisfy the concerns of Liguria Foods, and in October, 2013, Liguria Foods terminated the Griffith Laboratories relationship and began using a different spice supplier.

Background Information on Pepperoni Discoloration

Paprika is a spice used in pepperoni that provides the characteristic orange-red color of pepperoni. Paprika color is due to a mixture of carotenoids which include highly unsaturated fatty acids within the structure of the carotenoids (Carnevale et al., 1980. Exhibit 1 – attached to this report). The fatty acid content and chemical structure make paprika highly susceptible to oxidation by light and oxygen, resulting in pigment oxidation and loss of color (Cuvelier and Berset, 2005. Exhibit 2 – attached to this report). This phenomenon is widely recognized (Koncsek et al., 2016; Nishino et al., 2016), and the important role of antioxidants for maintenance of paprika color has been well-established (Biacs et al., 1992; Osuna-Garcia et al., 1997). The oxidation mechanism is essentially the same as that which occurs when meat lipids are oxidized to form rancid flavors, consequently, the conditions that favor lipid oxidation will result in both flavor changes in meat and color loss in paprika. Paprika color, however, is highly sensitive to oxidative conditions and can lose color quickly in an oxidative environment, a situation often exemplified by pepperoni where conditions that favor oxidation are a normal part of the production of this product.

Pepperoni is a dried sausage product that, after blending of meat with other ingredients, stuffing into casings and fermentation of the stuffed sausage, is exposed to temperatures of 50-55 °F and controlled circulating air to achieve the required drying process. The drying treatment is necessary because the United States Department of Agriculture-Food Safety and Inspection Service requires

pepperoni to have a moisture:protein ratio of 1.6:1 or less (www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_08205.pdf) in order to be properly labeled as pepperoni. Because fresh meat has a moisture : protein ratio of about 3.6:1, it is necessary to dry pepperoni to the point of approximately 30% weight loss in order to achieve the 1.6:1 moisture : protein ratio required. This requires a rather extensive drying treatment. Further, because the drying must be done slowly to achieve the desired product texture, the drying of pepperoni requires several days or weeks (depending on product size) of exposure to the relatively warm temperature of 50-55 °F and circulating air. These conditions are conducive to lipid oxidation and, consequently, use of antioxidants such as BHA and BHT is critically important to all dry sausage products, but especially so for pepperoni because of the sensitivity of paprika to oxidation and color loss.

Because of the relationship between meat lipid oxidation and paprika oxidation/color loss (one will accelerate the other), and the critical role of antioxidants for minimizing oxidation, problem-solving of color issues with pepperoni typically focuses first on two potential causes: meat fat quality issues and the antioxidants utilized for the product in question. However, several other causes may also need to be considered for a specific case of pepperoni discoloration. These include freeze/thaw treatments of both raw meat materials and the finished product, use of rework (adding a portion of previously finished product to the raw meat), product contact with sanitation chemicals and/or hard water, temperatures used for fermentation and drying, the packaging used for the finished product and product storage conditions. These additional potential causes for discoloration of pepperoni will be discussed in more detail relative to this case in the next section – Basis for Opinions.

Basis for Opinions

There does not appear to be a clear, cause-and-effect association between the spice mixture (no. 17-2112) and the product with the greatest number of customer complaints (19319 Regular Grind

Pepperoni). For example, James Whitham indicated in the Liguria Trip Report of 3/14/13 that the 17-2112 spice block was used in 3 pepperoni products produced by Liguria Foods (Whitham deposition, GLAB000478). These 3 products include 19319 Regular Grind Pepperoni, 19354 Coarse Grind Pepperoni and 19379 All Pork Pepperoni. Review of the complaint data for 2013 (LIGURIA/GRIFF 017112-017115) shows that the largest number of discoloration complaints (96), based on a total production of 16,458,322 lbs. in 2013 was for the 19319 Regular Grind Pepperoni, but only 4 complaints are noted for the 19354 Coarse Grind Pepperoni (production volume not shown) and only 1 complaint is recorded for the 19379 All Pork Pepperoni (production volume not shown). It should be noted that the 19354 Coarse Grind Pepperoni also included finely textured pork (LIGURIA/GRIFF 002182), a meat ingredient that is well-recognized as especially susceptible to oxidation (Calhoun et al., 1999) but this product resulted in relatively few customer complaints. It is also important to note that there were 25 discoloration complaints recorded for the 19290 AC Slicing Salami product which did not use the 17-2112 spice block (and presumably, because it is a salami product, did not include paprika). Because there were 827,048 lbs. of this product produced in 2013, it would appear that the discoloration complaints occurred at a significantly higher rate (0.0302 complaints per 1000 lbs.) for this product than for the 19319 Regular Grind Pepperoni (0.0058 complaints per 1000 lbs.) relative to the volume produced. Thus, it does not appear that there is a clear association between the 17-2112 spice block and the pepperoni discoloration problem. This suggests that other factors that impact pepperoni color stability may have contributed to the discoloration problem. The data on complaints and product volume are unclear however. There is no indication of the quantity of discolored products in each complaint, only the number of complaints, so it is not possible to determine how much actual product was affected in each complaint. The data on volume of production of the different products is also incomplete with the production volume for the 19354 Coarse Grind Pepperoni and the 19379 All Pork Pepperoni not

included. These were the two other pepperoni products in addition to the 19319 Regular Grind Pepperoni that utilized the 17-2112 spice block, and which resulted in few complaints.

Several other factors that contribute to pepperoni color stability exist as possibilities for color losses in this case. For example, frozen raw meat was used for the pepperoni formulation and it is well-known that oxidation reactions occur (albeit slowly) in frozen meat during storage (Leygonie et al., 2012. Exhibit 3 – attached to this report) because the radicals that result in lipid oxidation are found in the concentrated non-frozen portion of the meat during storage, and this concentration factor results in accelerated chemical reactions. Further, repeated freeze-thaw treatments such as occurred in this case for the raw materials initially and then for the finished product after frozen storage, increase the frequency and distribution of oxidized (TBARS-positive) areas within a meat block (Wu et al., 2016. Exhibit 4 – attached to this report).

Because of the variation in oxidative status that can occur with frozen meat, an objective measure of lipid oxidation is very useful to dry sausage manufacturers to assess a relative measure of fat quality of raw meat materials prior to use to assure that lipid oxidation is not excessive. It does not appear that Liguria Foods utilized any such check system for raw meat materials because the only analyses listed by Liguria Foods for the meat raw materials specifications are fat content and microbiological counts (LIGURIA/GRIFF 018813-018826). The Liguria Trip Report (GLAB00479) includes a comment that “an employee visually inspects the meat to assure that no green (bad) meat is used in the blends”. This would not be sufficient to detect meat that may already be oxidized. In fact, if meat is truly green in color, that would be an indication of very severe oxidation and almost certain product discoloration if used for pepperoni. Further, the use of visual checks suggests that some poor quality, discolored meat may have been observed at some point in the past. A subjective visual check during grinding and blending is unlikely to detect all possible problem meat materials. Some processors use a visual or odor assessment by employees but this is very subjective and does not represent a good

sampling or evaluative approach. While the meat used for the pepperoni in this case does not appear to have exceeded the recommended storage life for frozen meat, I found no record of frozen storage history in terms of temperature and time, or details of the thawing procedures used. These variables during storage and thawing can impact meat lipid oxidation, thus a chemical measurement of oxidation prior to use is a valuable means of assuring the oxidative quality of the meat used.

Another common issue with raw meat materials that has become a potential problem in dry sausage products is the use of dried distiller's grains with solubles (DDGS) in swine diets. While this is a highly nutritious feed component for swine, it is also high in unsaturated fatty acids and, depending on the amount fed in swine diets, can result in deposition of more unsaturated, softer fat on pork carcasses. The result is fat that is more prone to oxidation. Pepperoni in this case was analyzed for fatty acid profiles (JBACUS 000007), and showed a range of 12.99% to 17.07% of the total fat as polyunsaturated fatty acids (PUFA). Zhang et al. (2014. Exhibit 5 – attached to this report) reported a range of 9.61% to 13.84% PUFA for pigs on diets without DDGS, and Rauw et al. (2012. Exhibit 6 – attached to this report) reported a range of 18.2% to 19.6% PUFA in total fat for pigs on diets without DDGS. Finally, Shircliff et al. (2015. Exhibit 7 – attached to this report) compared fat quality in a group of control pigs with a group of pigs fed 20% DDGS, and reported that the controls had 14.23% - 15.98% PUFA and 13.86% - 14.19% linoleic acid as a % of total fat while the DDGS group had 17.72% - 21.32% PUFA and 18.49% - 19.42% linoleic acid as a % of total fat. Thus, DDGS does reduce pork fat quality but it is not clear if the values reported for meat in this case are problematic. Because the degree of fat unsaturation varies significantly with swine breeds (Zhang et al., 2014. Exhibit 5 – attached to this report), with location on the carcass (Lonergan et al., 1992), and between different muscles (Rauw et al., 2012. Exhibit 6 – attached to this report), there is considerable variation in fatty acid profiles introduced to product formulations using pork. Further, it does not appear that the values observed for the pepperoni in this case were unusually high relative to reported values for pork that was produced

without DDGS. However, the samples of the pepperoni analyzed in this case appear to be very limited in number and may not be truly representative of the product. A recommendation for dry sausage manufacturers that has become more common since the use of DDGS has been implemented for swine diets is to analyze fat of incoming raw materials for iodine value, which is a measure of unsaturation. Again, according to Liguria Foods raw materials specifications (LIGURIA/GRIFF 018813-018826), this does not appear to be done by Liguria Foods on a routine basis.

Another concern for meat ingredients that can result in pepperoni discoloration is use of rework. If rework has become partially oxidized prior to addition to the new batch, the radicals produced can result in accelerated oxidation in the rest of the batch. While some rework was used by Liguria Foods (LIGURIA/GRIFF 002182), it appears to have been used only in the 19354 Coarse Ground Pepperoni which had relatively few complaints (LIGURIA/GRIFF 017113), thus rework does not appear to be an issue in this case. However, the 19359 Coarse Ground Pepperoni appears to have used the 17-2112 spice block (Whitham deposition, GLAB 000478), thus for this product with rework, would represent a potentially greater susceptibility to oxidation, discoloration was not a major problem. On the other hand, James Whitham indicated in his deposition that "…bad pepperoni sample being sent to Griffith did contain rework…" (GLAB001459).

After consideration of meat materials, the second major concern for pepperoni color stability is the appropriate and adequate use of antioxidants and other ingredients such as nitrite (another important antioxidant ingredient). This is a critical consideration for dry sausage because the drying treatment places a strong oxidizing load on the product and even the best quality meat materials are likely to discolor quickly without appropriate antioxidant use. Clearly, both the amount and a uniform dispersion of the antioxidants are necessary to prevent discoloration of dry sausage. The Liguria Foods claim is that Griffith Laboratories failed to provide a uniformly dispersed mixture of BHA and BHT in the spice blocks due to "…(i) overloading the large volume mixers, which prevented the mix from being

thoroughly agitated and it's ingredients evenly and uniformly distributed; (ii) failing to mix the dry spices and additives for a sufficient period of time, (iii) having a lack of quality control procedures, and/or (iv) failing to implement an appropriate pre-mix system in order to allow smaller quantities of ingredients to be evenly mixed into the larger batches of the pepperoni spice mix." (Complaint and Jury Demand, no. 26).

Analysis of the spice mixtures for BHA and BHT content by Griffith Laboratories showed a range of 0.10% to 0.16% (LIGURIA/GRIFF 014982), a range that Liguria interpreted to indicate uneven dispersion of the antioxidants. However, even if uneven dispersion were the case, it is not possible, without further experimentation and testing, to conclude that the concentration on the low end of the range is insufficient for prevent pepperoni discoloration. The Rancimat data suggested that 20 ppm and 30 ppm of the antioxidants did not differ significantly (GLAB001082). Further, there are many analytical methods available for BHA and BHT (Andre´ et al., 2010), and they are variable in terms of relative standard deviations and measurement of uncertainty (Kim et al., 2016). While Griffith and ABC both used AOAC method 472.02 for measurement of BHA and BHT, the variation between these laboratories makes it clear that a certain degree of variability in the analyses is to be expected.

The third major consideration for pepperoni color stability is packaging because oxygen exposure accelerates oxidative reactions in meat. Again, paprika is particularly sensitive to oxygen exposure (Koncsek et al., 2016). Typical recommendations for oxygen-sensitive products such as pepperoni, include packaging in vacuum packages in the case of pepperoni sticks, or in gas-flushed packages in the case of pepperoni slices. Elimination of oxygen contact is an important means of extending the color life of pepperoni.

A significant amount of the pepperoni in this case appears to have been bulk packaged (GLAB000378) and in an unsealed bag exposed to air (Whitham deposition – GLAB001347). The Liguria

Trip Report (GLAB000478) also indicates that the discoloration was "…observed within the Bulk Packaging of the Pepperoni. No issues noted in the refrigerated, gas-flushed packaging." Further, James Whitham commented in his deposition that "…very little of the bulk pepperoni that we're dealing with here that was failing was in a gas-flushed environment." (Whitham deposition, p. 57). In a summary of Liguria Foods investigation of the discoloration problem, the packaging review is summarized as "All of the complaint products are on nonsealed bagged products…" (LIGURIA/GRIFF 001341). Liguria Foods further concludes that "the fact that 80% of all of our sliced pepperoni is packaged and sent out in this matter no consistent factor was found…" and that "…packaging is a non-factor". However, it is important to note that if other factors that affect pepperoni color are less than ideal, then packaging can be a very important factor, exacerbating the effect induced by the other causes of discoloration that may be involved.

The situation involving packaging is not clear however, in this case, because in the summary of customer complaints (Whitham exhibit 17 – LIGURIA/GRIFF 017112), the 19319 Regular Sliced Pepperoni, which had the greatest number of customer complaints is listed with both poly packaging (80% in 2012 and 83% in 2013) and gas-flushed packaging (18% in 2012 and 15% in 2013). Thus, information provided about packaging of the problem product is somewhat contradictory and not clear. However, since at least a large majority of the problem product (80% - 83%) was packaged in unsealed bulk packs, this product would be much more likely to discolor during frozen storage and thawing, particularly if other color controlling factors in the product were less than ideal.

Other causes of discoloration of pepperoni include meat contact with sanitation chemicals which are strong oxidizing compounds and which are sometimes not thoroughly rinsed off of equipment in the sanitation process, inappropriate bacterial populations during fermentation, use of unsoftened water and incorrect temperatures used during fermentation and drying that result in fat separation in

the product. However, there is insufficient information in the documents reviewed to assess the likelihood of these as factors in this case.

Conclusions and Opinions

Based on the above discussion, it is my opinion that there are several potential contributors to the discolored pepperoni in this case. While inadequate mixing and dispersion of the antioxidants in the spice block cannot be ruled out, I cannot find evidence that, to a reasonable degree of scientific certainty, shows the mixing of the spice block as the *only* potential cause of the discoloration. It is my opinion that the discoloration, described as "sporadic" and "not widely seen" (LIGURIA/GRIFF 002185) is more likely the result of a combination of factors that were less than ideal, and that, together, provided a cumulative effect that was significant enough to induce "sporadic" discoloration. Unfortunately, in the documents reviewed, I cannot find analytical data that supports a direct cause-and-effect relationship between the pepperoni discoloration and any one or series of factors important to color stability of this product.

The most effective way to resolve these questions would be to attempt to reproduce the discoloration problem in a controlled experiment. This could be done by utilizing a meat block that is split into two identical raw meat mixtures. One meat mixture would be used to manufacture pepperoni using the 17-2112 spice block at issue in this case, and the other meat mixture used to manufacture pepperoni with a spice block that has not been associated with any color issues. Subsequent processing, slicing, packaging and storage of the two pepperoni batches would then be done in identical fashion with assessment of discoloration following during storage for as long as necessary (such as 270 days or more) to determine if any difference in discoloration over time occurs in the two batches of pepperoni. Only if the spice block is the *only* variable involved in a comparison of products for development of discoloration, is it reasonable to conclude that the spice block is, or is not, the source of the

discoloration problem. In addition, a thorough examination of the pepperoni discoloration problem would require an analysis of Liguria's mixing procedures as well.

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Depositions and testimony: past 4 years – Joseph G. Sebranek

Deposition: April, 2015 in the case of BPI, Inc. v. ABC News

Testimony: none